

**Group III.** **Claims 41-54**, drawn to a method for delivering an immunomodulatory substance to a subject comprising contacting the skin of the subject with a device having a dermal-access means for accurately targeting the dermal space of the subject with an efficacious amount of the bioactive substance, classified in class 604, subclass 46.

**Group IV.** **Claims 55-90**, drawn to a method for delivering an immunomodulatory substance into tissue comprising delivering the substance within or beneath the skin at least into the intradermal space to access one or more compartments, classified in class 604, subclass 46.

The Examiner contends that the inventions of Groups I - IV are distinct from each other. Specifically, the Examiner alleges that inventions related to Groups I - IV are different methods with respect to starting materials, physiological mechanisms, protocol procedures, and end products. Applicant respectfully traverses the Restriction Requirement and respectfully requests a modification of the requirement so that Groups I - IV are combined and examined together in the instant application. For the reasons below, the subject matter of the claims merit examination in a single application. The claims of Groups I - IV are all directed to the same basic invention -- methods for delivering an immunomodulatory substance to the intradermal space of a subject. Moreover, the claims of Groups I - IV are all classified in class 604 and subclass 46. Since the claims of Groups I - IV are all classified in the same class and subclass, the prior art pertinent to one group will also be relevant to the other groups. Thus, contrary to the Examiner's contention, Applicant asserts that to search and examine the claims of Groups I - IV would not be a serious burden on the Examiner. The M.P.E.P. § 803 (Eighth Edition, Rev. 3, August 2005) states:

If the search and examination of all the claims in an application can be made *without serious burden*, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.  
(emphasis supplied)

Thus, in view of M.P.E.P. § 803, all of the claims of Groups I - IV should be searched and examined in the subject application. Accordingly, Applicant respectfully requests that the Restriction Requirement Under 35 U.S.C. § 121 be modified such that claims 1- 90 are examined in one application.

Notwithstanding the above, and in order to be fully responsive to the outstanding restriction requirement, Applicant hereby provisionally elects, with traverse, to prosecute the claims of Group II (Claims 22-40) without prejudice to Applicant's right to prosecute the non-elected subject matter in one or more continuation, continuation-in-part or divisional applications.

The Examiner has further required election of a species of substance for delivery as exemplified by claims 14, 16-20, 36-40, 50-54, and 69-73. Applicant hereby elects the species drawn to  $\alpha$  interferon for examination on the merits and believes that Claims 22-35, and 40 each read on the elected species.

### CONCLUSION

Entry of the foregoing amendments and consideration of the remarks is respectfully requested. The claims are believed to be patentable and free of the art. Early allowance is respectfully requested.

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